DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–67–03]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498–1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project: Possession, Use, and Transfer of Select Agents and Toxins (42 CFR part 73) (OMB Control No. 0920–0576)—Revision—Office of the Director (OD), Centers for Disease Control and Prevention (CDC). The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188) specifies that the Secretary of Health and Human Services shall provide for the establishment and enforcement of standards and procedures governing the possession, use, and transfer of select biological agents and toxins. The Act specifies that facilities that possess, use, and transfer select agents register with the Secretary. The Secretary has designated CDC as the agency responsible for collecting this information.

CDC is requesting continued OMB approval to collect this information through the use of five separate forms. This request reflects revisions to the forms approved in February, 2003 as a result of public comments to the Interim Final Rules that CDC and USDA/APHIS published in February, 2003. These forms are: (1) Application for Registration; (2) Facility Notification Form; (3) Request for Exemption; (4) Transfer of Select Agent form; and (5) Clinical and Diagnostic Laboratory Reporting Form. The revisions to the forms are primarily changes to the Guidance documents to clarify instructions and the inclusion of a supplemental form to the Application form for Biosafety Level 4 (BSL4) laboratories. CDC is requesting a 3-year approval for this data collection.

The Application for Registration will be used by facilities to register with CDC. The Application for Registration requests facility information, a list of select agents in use, possession, or for transfer by the facility, characterization of the select agent, and laboratory information. Estimated average time to complete this form is 3 hours, 45 minutes for an entity with one principal investigator working with one select agent. CDC estimates that entities will need an additional 45 minutes for each additional investigator or select agent. BSL4 laboratories will also complete and submit Section 6 of the Application for Registration. CDC is requesting OMB approval to add this section to the Application for Registration because of the unique data required for these facilities. We identified the need for this section during the registration process following the February, 2003 approval of the Application form. Although there are less than 10 respondents for this form, CDC has decided to voluntarily comply with the Paperwork Reduction Act and seek OMB approval for this form. Estimated time to complete and submit Section 6 is 2 hours.

Facilities may amend their registration if any changes occur in the information submitted to the Secretary. To apply for an amendment to a certificate of registration, an entity must obtain the relevant portion of the application package and submit the information requested in the package to CDC. Estimated time to amend a registration package is 60 minutes.

The Facility Notification Form must be completed by facilities whenever there is release of a select agent or theft or loss of a select agent. Estimated average time to complete this form is 60 minutes.

The Request for Exemption form will be used by facilities that are using select agents in investigational new drug testing or in cases of public health emergency. Estimated average time to complete this form is 70 minutes.

The Transfer of Select Agent Form will be used by facilities requesting transfer of a select agent to their facilities and by the facility transferring the agent. Estimated average time to complete this form is 1 hour, 45 minutes.

The Clinical and Diagnostic Laboratory Exemption Report will be used by clinical and diagnostic laboratories to notify the Secretary that select agents identified as the result of diagnosis or proficiency testing have been properly disposed of. Estimated average time to complete this form is 60 minutes.

In addition to the standardized forms, this regulation also outlines situations in which an entity must notify or make a request of the Secretary in writing and CDC is requesting OMB approval to collect this information. The regulation states that an entity must notify the Secretary in writing at least five business days before destroying all select agent or toxin covered by a certificate of registration. The estimated time to gather the information and submit this notification is 30 minutes.

An entity may also apply to the Secretary for an expedited review of an individual by the Attorney General. To apply for this expedited review, an entity must submit a request in writing to the Secretary establishing the need for such action. The estimated time to gather the information and submit this request is 30 minutes. Entities should be aware that CDC is not developing standardized forms to use in these situations. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

As part of the safety requirements of this regulation, the Responsible Official is required to conduct regular inspections (at least annually) of the laboratory where select agents and toxins are stored. The results of these inspections must be documented. CDC estimates that, on the average, such documentation will take 1 hour.

Also, as part of the safety requirements of this regulation, the entity is required to record the identity of the individual trained, the date of training, and the means used to verify that the employee understood the training. Estimated time for this documentation is 2 hours per principal investigator.

An entity or an individual may request administrative review of a decision denying or revoking either a certification of registration or approval based on a security risk assessment. This request must be in writing within 30 calendar days after the adverse decision. This request should include a statement of the factual basis for the review. CDC estimates the time to prepare and submit such a request is 4 hours.

Finally, an entity must implement a system to ensure that certain records and databases are accurate and that the authenticity of records may be verified. The time to implement such a system is estimated to average 4 hours. Total annualized burden for this data collection is 17,905 hours.

CFR reference	Data collection	No. of respondents	Responses per respondent	Avg burden per response (in hrs.)
73.7(b)	Registration Application	575	1	3.75
73.7(b)	BSL4 Supplement	4	1	2
73.7(e)	Amendment to Registration Application	575	2	1
73.17(a)(e)	Notification Form	10	1	1
73.6(c-e)	Request for Exemption	17	1	1.16
73.14	Transfer of Select Agent	575	5	1.75
73.6(a)(2)	Clinical and Diagnostic Laboratory Exemption Report	1,000	4	1
73.7(i)	Notification of Inactivation	6	1	30/60
73.8(g)	Request Expedited Review	6	1	30/60
73.10(b)	Documentation of Self-inspection	575	1	1
73.13(f)	Documentation of Training	575	1	2
73.18	Administrative Review	14	1	4
73.15(d)	Ensure Secure Record keeping System	575	1	30/60

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Nancy Cheal,

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Proposed Project

Menthol Crossover Study—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC). CDC proposes a study to measure differences in African-American and Caucasian smokers in the dose and metabolism of chemicals in smoke from menthol and non-menthol cigarettes.

African-American smokers are more likely than Caucasian smokers to develop some forms of cancer and to have shorter long-term survival after diagnosis. More than 65% of African American smokers smoke menthol cigarettes, compared with about 23% of white smokers. Smoking menthol cigarettes has been associated with higher blood-cotinine levels. Cotinine is a product of the metabolism of nicotine, and the higher cotinine levels suggest that menthol may enable a smoker to obtain more nicotine from each cigarette. In addition, people who smoke menthol cigarettes also have higher levels of carbon monoxide in their breath than do people who smoke non-menthol cigarettes, and an elevated carbon monoxide level is a risk factor for cardiovascular disease. Additionally, the presence of menthol in cigarettes may change the way people smoke cigarettes.

All previous studies have compared people who smoke menthol cigarettes with those who smoke non-menthol cigarettes; and it is not known whether increased cotinine and carbon monoxide levels in people who smoke menthol cigarettes are attributable to racial or ethnic differences, or a combination of multiple factors. In addition, no previous study has examined the differences between urinary levels of cancer-causing chemicals in people who smoke menthol or non-menthol cigarettes and correlated these findings with smoke exposure intake estimates using salivary cotinine and filter solanesol.

For this two-part crossover study, we will recruit African-American and Caucasian smokers of both sexes who smoke either menthol or non-menthol cigarettes as study subjects. We will determine smoking history then randomly assign each participant to smoking either menthol or non-menthol cigarettes for an initial 2-week period. Study participants then will switch to the opposite type of cigarette for the next 2 weeks. At baseline, and after each 2-week period, we will measure the way the participants smoke the test cigarettes to determine smoking topography. Saliva, urine, and breath samples will be collected to measure by-products of smoking, and participants will complete a brief smoking-history questionnaire. There is no cost to respondents.

Forms	No. of respondents	No. of responses/respondent	Average burden/response (in hours)	Total burden in hours
Response to Flyer: Screening Interview Form	200	1	5/60	17
Site Visits: Check in, Study Information, Visit 1, 2, 3	71	3	15/60	53
Consent Form, Questionnaire, Visit 1, 2, 3	71	3	15/60	53
Urine Sample and Saliva Sample, Visit 1, 2, 3	71	3	15/60	53
Breath Carbon monoxide (CO) Sample: Test Smoke 1, Breath CO Sample; Test Smoke 2, Breath CO Sample; Visit 1, 2, 3	71	3	45/60	160
Sample Test Cigarettes, Distribute Baggies & Cigarettes, Visit 1 and 2	71	2	15/60	36
Instructions and Check out, Visit 1 and 2	71	2	15/60	36
Smoking Cessation Advice, Visit 3 only	71	1	15/60	18